510(k) Summary For K122273
MENICON PROGENT PROTEIN REMOVER FOR RIGID GAS PERMEABLE CONTACT LENSES

JAN 0 2 2013

November 30, 2012

1. Applicant Information

Menicon Co., Ltd.
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Naka-ku, Nagoya 460-0006
JAPAN

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Summary prepared on:	November 30, 2012

2. Device Information

Classification name:	Rigid gas permeable contact lens care products
Device classification:	Class II
Regulation number:	21 CFR 886.5918
Product code:	MRC
Proprietary name:	Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

3. Predicate Devices

Menicon claims substantial equivalence to Menicon Progent Protein Remover for Rigid Gas Permeable Contact (RGP) Lenses previously cleared under K002140 and K082855.

4. Description of device

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is the mixture of two sterile solutions, Progent A (active ingredient, sodium hypochlorite) and Progent B (active ingredient, potassium bromide). Progent A and B are mixed in a Menicon SP Vial. Allow lenses to soak in the Progent solution mixture for 30 minutes. Soaking for longer than 30 minutes is not recommended. The Progent treatment is recommended every two weeks. The frequency may vary according to the condition of your lens. Follow your eye care professional's directions (to a maximum of every 5 days).

5. Indications for use

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate RGP contact lenses.

6. Substantial equivalence

The claim of substantial equivalence to the previously cleared Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is based on the fact that the active components of the protein remover system (Progent Solution A and Progent Solution B) are the same formulation as the predicate devices. The only change is the addition of an alternative rinsing solution, sterile normal saline, versus sterile purified water cleared in 510(k) K082855..

In support of this application, nonclinical testing (Residual Progent Testing) was done to prove that the rinsing effectiveness of the new rinsing solution, sterile normal saline, was equivalent to the rinsing solution used in the previously cleared 510(k) K0828 55, sterile purified water.

Residual Progent Testing was performed to determine the amount of residual Progent Solution that remains following the lens rinsing process. Rinsing solutions were collected and measure to determine the remaining active chlorine concentration and pH of the rinsing solutions.

6. **Substantial equivalence** (continued)

This test was originally performed in 2009 with the sterile purified water used as a rinsing solution in K082855. In support of this application the test was repeated with sterile normal saline as a rinsing solution. A comparison of the two sets of data was completed and based on active chlorine concentrations and pH values it was confirmed that the rinsing efficacy of sterile normal saline was equal to the rinsing efficacy of the sterile purified water.

Based on these results the Menicon Progent Protein Remover for RGP Contact Lenses with sterile saline rinse is substantially equivalent to the Menicon Progent Protein Remover for RGP Contact Lenses with sterile purified water rinse.

In addition the Progent solutions may be manufactured at an alternate manufacturing site, Gujo Factory, Menicon Nect, Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 0 2 2013

Menicon Co., Ltd.
% Ms. Ellen M. Beucler
Foresight Regulatory Strategies, Inc.
187 Ballardvale Street, Suite 180
Wilmington, MA 01887

Re: K122273
Trade/Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid gas permeable contact lens care products
Regulatory Class: Class II
Product Code: MRC
Dated: November 30, 2012
Received: December 6, 2012

Dear Ms. Beucler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122273

Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K122273